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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,266	03/28/2001	Agamemnon Antoniou Epenetos	JG-EPC-4955P/500563.20004	4300

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/819,266	EPENETOS, AGAMEMNON ANTONIOU	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-III. Claims 1, 3, 10-16, 21-22, drawn to a compound comprising a target cell-specific portion and a cytotoxic portion, which is a caspase-3 or caspase-6 or caspase-7, classified in class 530, subclass 350. It is noted that claim 1 is an improper implied Markush claim, since it is clearly meant to encompass different compounds comprising different caspases. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 1 do not share a common property, nor do they function by a common mechanism to induce apoptosis. Thus claims 1, 3, 10-16, 21-22 are drawn to three distinct compounds comprising a target cell-specific portion and different caspases. Each of the compound comprising a target cell-specific portion and a single caspase is a separate invention, that is a separate group, and **not a species**. Applicant is required to elect a single group. Claims 1, 3, 10-16, 21-22 will be examined as they are drawn to the elected group.

IV-VI. Claims 2, 4-9, drawn to a compound comprising a mediator portion capable of recognize a cell-specific molecule and a cytotoxic portion, which is a caspase-3 or caspase-6 or caspase-7, classified in class 530, subclass 350. It is noted

that claim 2 is an improper implied Markush claim, since it is clearly meant to encompass different compounds comprising different caspases. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 1 do not share a common property, nor do they function by a common mechanism to induce apoptosis. Thus claims 2, 4-9 are drawn to three distinct compounds comprising a mediator portion and different caspases. Each of the compound comprising a mediator portion and a single caspase is a separate invention, that is a separate group, and **not a species**. Applicant is required to elect a single group. Claims 2, 4-9 will be examined as they are drawn to the elected group.

VII-X. Claims 17-20, drawn to a nucleic acid molecule encoding to a compound comprising a target cell-specific portion and a cytotoxic portion, which is a caspase-3 or caspase-6 or caspase-7, classified in class 536, subclass 23.1. It is noted that claim 1, to which claim 17 is dependent, is an improper implied Markush claim, since it is clearly meant to encompass different compounds comprising different caspases. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior

art that all of them possess this property. The members of the implied Markush groups recited in claim 1 do not share a common property, nor do they function by a common mechanism to induce apoptosis. Thus claims 17-20 are drawn to three distinct nucleic acid molecules encoding compounds comprising a target cell-specific portion and different caspases. Each of the nucleic acid molecules encoding a compound comprising a target cell-specific portion and a single caspase is a separate invention, that is a separate group, and **not a species**. Applicant is required to elect a single group. Claims 17-20 will be examined as they are drawn to the elected group.

XI. Claims 17-20, drawn to a nucleic acid molecule encoding to a compound comprising a target cell-specific portion, classified in class 536, subclass 23.1.

XII. Claims 17-20, drawn to a nucleic acid molecule encoding to a compound comprising a mediator portion, classified in class 536, subclass 23.1.

XIII-XV. Claims 17-20, drawn to a nucleic acid molecule encoding to a compound comprising a cytotoxic portion, which is a caspase-3 or caspase-6 or caspase-7, classified in class 536, subclass 23.1. It is noted that claim 17 is an improper implied Markush claim, since it is clearly meant to encompass different nucleic acid molecules encoding different caspases. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 17 do not share a common

property, nor do they function by a common mechanism to induce apoptosis. Thus claims 17-20 are drawn to three distinct nucleic acid molecules encoding different caspases. Each of the nucleic acid molecules encoding a single caspase is a separate invention, that is a separate group, and **not a species**. Applicant is required to elect a single group. Claims 17-20 will be examined as they are drawn to the elected group.

XVI-XVIII. Claims 23-27, drawn to a method for treating diseases or cancer, comprising administering a compound comprising a target cell-specific portion and a cytotoxic portion, which is a caspase-3 or caspase-6 or caspase-7, classified in class 514, subclass 4. It is noted that claim 1, the compound of which is used in claims 23-27, is an improper implied Markush claim, since it is clearly meant to encompass different compounds comprising different caspases. Further, MPEP 2173.05(h) provides that when the Markush group occurs in a claim reciting a process or a combination it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property. The members of the implied Markush groups recited in claim 1 do not share a common property, nor do they function by a common mechanism to induce apoptosis. Thus claims 23-27 are drawn to three distinct methods using three distinct compounds comprising a target cell-specific portion and different caspases. Each of the method using a compound comprising a target cell-specific portion and a single caspase is a separate invention, that is a separate group, and **not a species**.

Applicant is required to elect a single group. Claims 23-27 will be examined as they are drawn to the elected group.

The inventions are distinct, each from each other because of the following reasons:

Inventions (I-XV) and (XVI-XVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein.

The products of groups I-XV are patentably distinct, because they are drawn to entirely different biochemicals , having different structures, biological properties and activities.

The methods of groups XVI-XVIII are distinct from each other because they differ at least in reagents and/or dosages, and/or schedules used, response variables and criteria for success.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

May 4, 2002

SUSAN UNGAR, PH.D
PRIMARY EXAMINER